



NDA 20857/S-034

**SUPPLEMENT APPROVAL**

ViiV Healthcare Company  
Attention: Stephen Hyatt, RAC  
Project Manager, Global Regulatory Affairs  
Five Moore Drive  
PO Box 13398  
Research Triangle Park, NC 27709

Dear Mr. Hyatt:

Please refer to your Supplemental New Drug Application (sNDA) dated and received November 13, 2018, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for COMBIVIR (lamivudine and zidovudine) tablets, 150 mg and 300 mg.

This Prior Approval supplemental new drug application provides for the following revisions to the Prescribing Information:

- To update USE IN SPECIFIC POPULATIONS, Pregnancy subsection with information on hyperlactatemia reported in neonates and infants exposed in utero or peripartum to zidovudine-containing products.

**APPROVAL & LABELING**

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

**CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As” at <http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

### **REPORTING REQUIREMENTS**

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call CAPT Anitra Johnson, DHSc, MSN, RN, Regulatory Project Manager, at (301) 796-4876.

Sincerely,

*{See appended electronic signature page}*

Debra Birnkrant, MD  
Director  
Division of Antiviral Products  
Office of Antimicrobial Products  
Center for Drug Evaluation and Research

### ENCLOSURE:

Content of Labeling  
Prescribing Information

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**This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.**  
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/s/  
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POONAM MISHRA  
05/10/2019 12:06:13 PM  
on behalf of Debra Birnkrant